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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/578,765	03/20/2007	Mahendra G. Dedhiya	MERZ 49 PCT US	1522

25666 7590 12/04/2008
THE FIRM OF HUESCHEN AND SAGE
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EXAMINER

THOMAS, TIMOTHY P

ART UNIT	PAPER NUMBER
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1614

MAIL DATE	DELIVERY MODE
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12/04/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/578,765	Applicant(s) DEDHIYA ET AL.	
	Examiner TIMOTHY P. THOMAS	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 August 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7, 13-32, 39-41, 44, 45 and 48-55 is/are pending in the application.
- 4a) Of the above claim(s) 23-25, 27-32, 45 and 48-55 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 13-22, 26, 39-41 and 44 is/are rejected.
- 7) ☒ Claim(s) 44 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/18/2008</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Priority

1. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged.
2. The Application Data Sheet filed 8/18/2008 properly establishes the benefit claim to provisional U.S. application No. 60/517981, filed 11/5/2003.

Response to Arguments

3. Applicants' arguments, filed 8/18/2008, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.
4. Applicant continues to argue that the amended claims do not lack unity of invention, arguing that the "special common technical feature" is a preservative free aqueous-based neramexane composition. This argument is not persuasive for the reasons of record, and the rejections that are presently applied to the claims under examination. The request to examine claims 45 and 48-55 is taken as a request for rejoinder. However, no rejoinder is made at this time since the elected species is not presently considered allowable.
5. The following claim objection is maintained:

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Claim 44 is objected to because of the following informalities: there are two periods in the claim, which are not at the end of the sentence, after the letters a and b. Appropriate correction is required.

6. Applicant's arguments with respect to the rejection of claims 1-3, 6-7, 12, 14-22 and 39-40 under 35 USC 102 have been fully considered but they are not persuasive:

Claims 1-3, 6-7, 14-22 and 39-40 are rejected under 35 U.S.C. 102(b) as being anticipated by Parsons et al. (WO 01/98253 A2; 2001 Dec).

The rejection is maintained for the reasons of record. Claim 12 is canceled.

Applicant argues that Parsons does not specifically disclose preservative free compositions comprising neramexane or a pharmaceutically acceptable salt thereof. This is not persuasive. The disclosure of the elected compound, 1-amino-1,3,3,5,5-pentamethylcyclohexane (neramexane; p. 6, middle; p. 8, 1st named compound; p. 51 table, MRZ 579) and the HCl salt of neramexane (MRZ 2/579; p. 2, 1st named compound) as active ingredients of the Parsons teaching along with Example 4, that names Active Ingredient, Sodium chloride and sterile water would permit one of ordinary skill in the art to immediately envisage the solution of example 4 where neramexane and neramexane HCl are used as the active ingredient. These solutions for injections do not name a preservative, and are therefore "preservative free", anticipating the claims.

7. Applicant's arguments with respect to the rejection of claims 1, 4-5 and 39-41 under 35 USC 103 have been fully considered but they are not persuasive:

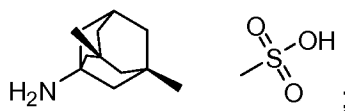
Claims 1, 4-5 and 39-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Parsons et al. (WO 01/98253 A2; 2001 Dec).

No arguments are presented, only a summary of the rejection basis. Therefore, the rejection is maintained for the reasons of record.

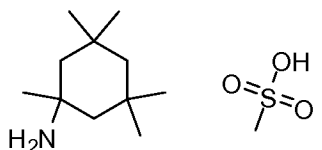
8. Applicant's arguments with respect to the rejection of claims 1, 13, 26, and 44 under 35 USC 103 have been fully considered but they are not persuasive:

Claims 1, 13, 26 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Parsons et al. (WO 01/98253 A2; 2001 Dec) and Gupta et al. (US 2005/0014743 A1; priority 2003 May).

Applicants argue there is not teaching in the Parsons disclosure to suggest the surprising /unexpected anti-microbial properties associated with neramexane, disclosed in the instant specification, for example as pages 25-27. It is noted that applicant has demonstrated antimicrobial activity of memantine mesylate, and it appears that neramexane mesylate is interchanged with memantine mesylate, from the description in paragraph 0077 and Tables 7-10. However, memantine mesylate has the structure:



a different compound from neramexane mesylate, which has the structure:



Since these two compounds have different structures, and the Tables list results for Memantine mesylate solutions, unexpected results are not considered to have been

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demonstrated for the neramexane mesylate compositions of the claims, on which the rejection is based. Applicant is invited to provide evidence of unexpected results for neramexane mesylate, to demonstrate the position argued.

Conclusion

9. No claim is allowed.

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TIMOTHY P. THOMAS whose telephone number is (571)272-8994. The examiner can normally be reached on Monday-Thursday 6:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Timothy P Thomas/
Examiner, Art Unit 1614

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614